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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|--------------------------|---------------------|------------------|
| 09/646,925 | 01/31/2001 | Steven Neville Chatfield | 117-320 | 2850 |
| 23117 | 7590 | 03/14/2005 | EXAMINER | |
| NIXON & VANDERHYE, PC | | | FORD, VANESSA L | |
| 1100 N GLEBE ROAD | | | | |
| 8TH FLOOR | | | ART UNIT | PAPER NUMBER |
| ARLINGTON, VA 22201-4714 | | | 1645 | |

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|---|------------------------|---------------------------|
| Response to Rule 312 Communication | Application No. | Applicant(s) |
| | 09/646,925 | CHATFIELD, STEVEN NEVILLE |
| | Examiner | Art Unit |
| | Vanessa L. Ford | 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. The amendment filed on 01 October 2004 under 37 CFR 1.312 has been considered, and has been:

- a) entered.
- b) entered as directed to matters of form not affecting the scope of the invention.
- c) disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.
- d) disapproved. See explanation below.
- e) entered in part. See explanation below.

Claim 16 was indicated as being withdrawn. Claim 16 was rejoined in light of In re Ochiai and is allowed. See interview Summary dated July 26, 2004. Therefore, the following Examiner's amendment is made to indicate that claim 16 is allowed. Please see attached clean copy of allowed claims.

Lynette R. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary Tanigawa on March 3, 2005.

In the claims:

A. Claim 16. (original) A method of raising an immune response in an mammalian host, which comprises administering to the host an *Escherichia coli* bacterium as defined in claim 1.

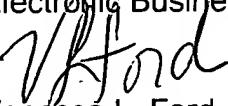
Conclusion

2. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
August 3, 2004

CLEAN COPY OF CLAIMS

1. An *Escherichia coli* bacterium attenuated by a non-reverting mutation in each of the *aroC* gene, the *ompF* gene and the *ompC* gene.
5. An *Escherichia coli* bacterium according to claim 1 which is a strain of enterotoxigenic *E. coli* (ETEC).
6. An *Escherichia coli* bacterium according to claim 1 which is further attenuated by a mutation in a fourth gene.
7. An *Escherichia coli* bacterium according to claim 6 wherein the fourth gene is selected from the group consisting of *aroA*, *aroD*, *aroE*, *pur*, *htrA*, *galE*, *cya*, *crp*, *phoP* and *surA*.
8. An *Escherichia coli* bacterium according to claim 1, wherein the mutation in each and every gene is a defined mutation.
9. An *Escherichia coli* bacterium according to claim 1, wherein the mutation in each and every gene is deletion of the entire coding sequence.
10. An *Escherichia coli* bacterium according to claim 1 which has been genetically engineered to express a heterologous antigen.
11. An *Escherichia coli* bacterium according to claim 10, wherein expression of the antigen is driven by the *nirB* promoter or the *htrA* promoter.
16. A method of raising an immune response in an mammalian host, which comprises administering to the host an *Escherichia coli* bacterium as defined in claim 1.

17. An *Escherichia coli* bacterium according to claim 1, which is PTL003 deposited on September 3, 2001 under accession number 01090302 with the European Collection of Cell Cultures (ECACC).